

diarrhoea) from irinotecan-based regimens are not readily available, experts were asked to provide frequency estimates and resources associated with management. Descriptive statistics were used to summarise the data. **RESULTS:** The final expert panel comprised 44 oncologists representing all English NHS regions, from a sample of 98 potential experts. Wide variations in prescribing practice were identified. There were ten first-line, ten second-line and twelve third-line chemotherapy regimens reported, reflecting variation in practice. However, dominant treatment pathways emerged for each stage of treatment, with: first-line treatment with oxaliplatin-based regimens, second-line treatment with irinotecan-based regimens, and third-line treatment with mitomycin-based regimens. Experts estimated the frequency of: febrile neutropaenia 8.4% (95% CI: 6.7–10.0), septic neutropaenia 4.7% (95% CI: 3.4–6.0), and severe diarrhoea 13.1% (95% CI: 10.8–15.5). **CONCLUSIONS:** This study captured the heterogeneity in chemotherapy prescribing practice and patient management within CRC specialties and obtained necessary data to inform the appropriate model structure for base case and subsequent structural and parameter sensitivity analyses.

## PCN172

#### TREATMENT PATTERNS AMONG PATIENTS WITH ADVANCED BREAST CANCER PREVIOUSLY TREATED WITH AN ANTHRACYCLINE AND A TAXANE: A RETROSPECTIVE LONGITUDINAL STUDY

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**OBJECTIVES:** Current treatment practices for patients in Australia with advanced breast cancer (ABC) who have previously been treated with an anthracycline and a taxane (A&T) are not well defined. There is no "gold standard" treatment for these heavily pre-treated patients. A retrospective longitudinal survey was conducted to gain an insight into the treatments currently used in this patient group. **METHODS:** Four public hospitals provided patient level data. Inclusion criteria encompassed women  $\geq 18$  years with ABC who had previously received A&T therapy and had  $\geq 3$  months follow-up. Information on demographics, disease characteristics and treatment history was obtained from medical records of all eligible patients. Descriptive statistics were performed by disease characteristics and treatments prescribed by line of therapy post A&T. **RESULTS:** Data were obtained from 79 patient records. The mean (SD) age at initial diagnosis was 51.5 (10.9) years with most patients having stage IIIA disease (45.6%). Seventy four patients (93.7%) had previously undergone surgery. The most common first-line therapies post A&T were monotherapy or combination use of radiotherapy (39/79, 49.4%), cytotoxic chemotherapy (36/79, 45.6%), targeted therapy (11/79, 13.9%) and hormonal therapy (8/79, 10.3%). Paclitaxel, whether used alone or in combination, was the most common first-line cytotoxic treatment post A&T (11/79, 13.9%), followed by cyclophosphamide (10/79, 12.7%), doxorubicin (9/79, 11.4%) and docetaxel (7/79, 8.9%). Cytotoxic mono-chemotherapies were more commonly prescribed first-line post A&T than cytotoxic combination treatments (31.6% vs. 13.9%) with paclitaxel (9/79, 11.4%), docetaxel (5/79, 6.3%) and capecitabine (4/79, 5.1%) being most frequently prescribed. FEC (4/79, 5.1%) and doxorubicin/cyclophosphamide (3/79, 3.8%) were the most commonly administered cytotoxic first-line combinations. **CONCLUSIONS:** The considerable variation in the treatments prescribed for patients with ABC who have previously received A&T highlight the need for an effective treatment option. Radiotherapy and cytotoxic chemotherapy were the most frequently administered therapies, with paclitaxel being most commonly prescribed cytotoxic agent.

#### INDIVIDUAL'S HEALTH – Clinical Outcomes Studies

## PIH1

#### PERCEPTION OF PAIN AFTER CAESAREAN SECTION FROM THE POINT OF VIEW OF PUERPERAL MOTHERS

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**OBJECTIVES:** Pain, such as pain following Caesarean section is a subjective and complex experience, from the intensity of which we can get a forecast with the respect of a number of influencing factors. The aim of this study is to examine those factors that influence postoperative pain after Caesarean section. **METHODS:** Our examination was made among women and went through a Caesarean section University of Pécs Obstetric and Gynecology Clinic and Hospital of Baranya County between October 1, 2008 and December 31, 2008 in Hungary. Our own questionnaire and a numerical classifier scale were used to measure the intensity of pain. Under the examination time we got back altogether 183 valuable questionnaires from the two institutions.  $\chi^2$  test, t-test, ANOVA variance analysis, Pearson-Spearman correlation coefficient examination was used for the analysis. Data processing was done with SPSS 15.0 and MS Excel programs. **RESULTS:** Based on the results of our research a significant connection can be shown through the examination of postoperative pain following Caesarean section in case of school ( $p = 0.01$ ), the method of anesthesia ( $p = 0.002$ ;  $p = 0.041$ ) and the memory of the previous Caesarean section ( $p = 0.03$ ;  $p = 0.008$ ). **CONCLUSIONS:** According to the results of our study those who had higher qualification had higher postoperative pain intensity and lower functional activity than mothers with lower qualifications. Examining the anesthesia method we can say that those mothers who were narcotized reported bigger postoperative pain than those mothers who got epidural anesthesia.

## PIH2

#### ADVERSE EVENTS ASSOCIATED WITH THE USE OF SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRI'S) ANTIDEPRESSANT MEDICATIONS AMONG CHILDREN: A REVIEW OF THE FDA ADVERSE EVENT REPORTING SYSTEM (AERS)

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**OBJECTIVES:** To examine the adverse events in children treated with SSRIs reported through the FDA's Adverse Event Reporting System in response to the increased risks of suicide among children being treated with antidepressants. **METHODS:** A retrospective pharmacovigilance analysis was conducted using the January 2004 to September 2006 FDA Adverse Event Reporting System (AERS) data. The adverse drug event cases (ADEs) associated with SSRI antidepressants were identified based on the role of the medication in the incidence of the ADEs as the Primary and Secondary suspect. Children were defined as patients below 18 years. **RESULTS:** Out of 68,936 ADE cases involving SSRI antidepressants, the SSRIs were identified as the primary suspect in 27,075 cases and as the secondary suspect in 6,713 cases. Of those cases, there were merely 1,780 (5.26%) cases involving children. The number of cases reported to the FDA per quarter was 161.81 on an average for the 11 quarters data. Paroxetine accounted for the majority of the reported ADE, 778 (43.70%) cases involving children followed by Sertraline 315 (17.69%) and Escitalopram 273 (15.33%). Despite the low reporting rate, adverse events associated with SSRI antidepressants can have serious consequences. Suicide attempt was reported in 579 cases (16.88%) followed by psychotic disorders in 420 cases (12.24%). More than one third (608, 38.23%) of those cases led to hospitalization. **CONCLUSIONS:** Despite that the adverse events reported for SSRI antidepressants being taken by children were low; the consequences of those adverse events can be very serious. Suicide attempt was the most commonly reported adverse event. Paroxetine was the most common SSRI to be reported for adverse events and the main outcome was hospitalization.

## PIH3

#### DUTASTERIDE PLUS TAMSULOSIN PROVIDES SUPERIOR IMPROVEMENTS IN PATIENT-REPORTED QUALITY OF LIFE: 4-YEAR RESULTS FROM THE COMBINATION OF AVODART® AND TAMSULOSIN (COMBAT) STUDY

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**OBJECTIVES:** Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) represent a significant burden in affected men, with increasingly severe LUTS associated with a lower quality of life (QoL). 2-year primary analyses of the CombAT study ( $n = 4844$ ) showed that dutasteride plus tamsulosin provided significantly greater symptom and QoL improvement versus either monotherapy. Here we present 4-year data on the effects of dutasteride plus tamsulosin compared with each monotherapy on the patient-reported health outcomes, BPH Impact Index (BII) and International Prostate Symptom Score (IPSS) Q8. **METHODS:** Following screening, eligible subjects entered a single-blind run-in period during which they received dutasteride and tamsulosin placebos for four weeks. All subjects were then randomised to receive 0.5 mg dutasteride, 0.4 mg tamsulosin or the combination once daily for 4 years. The primary endpoint for the 4-year analysis was time to acute urinary retention or BPH-related surgery; secondary endpoints included change from baseline in IPSS, BII and IPSS Q8. **RESULTS:** At baseline, mean BII and IPSS Q8 were 5.3 and 3.6, respectively, in all three treatment groups. Mean change from baseline in BII at Month 48 was  $-2.2$  with combination therapy,  $-1.8$  with dutasteride and  $-1.2$  with tamsulosin (both  $p < 0.001$  versus combination). For IPSS Q8, the corresponding values were  $-1.5$  with combination,  $-1.3$  with dutasteride and  $-1.1$  with tamsulosin (both  $p < 0.001$  versus combination). Improvement in BII and IPSS Q8 from baseline with combination therapy was statistically greater than with dutasteride from 3 months; compared with tamsulosin, the improvement from baseline with combination was statistically greater from 9 months (BII) and 12 months (IPSS Q8). **CONCLUSIONS:** Dutasteride combined with tamsulosin delivers superior improvement in health outcomes (BII and IPSS Q8) versus either monotherapy. The superiority of combination therapy over dutasteride was observed from three months, and over tamsulosin as early as nine months.

## PIH4

#### ROLE OF LIFESTYLE-RELATED FACTORS IN PELVIC FLOOR MUSCLE STRENGTH CHANGES DURING PREGNANCY

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**OBJECTIVES:** To assess strength and duration of pelvic floor muscle (PFM) contraction and to monitor the changes of lifestyle-related factors (body weight, constipation, vaginal wall laxity and physical activity) during pregnancy. **METHODS:** Our study focused on examining the strength and duration of pelvic floor muscle contraction in pregnant women during the 2nd and 3rd trimesters. Parameters were measured by a device for measuring vaginal pressure. Statistical data were calculated according to mean, standard deviation, T-test methods and the results were considered to be relevant at  $p < 0.05$ . **RESULTS:** Data of 93 women were analyzed. The maximum muscle strength of nulliparous women ( $n = 36$ ) was significantly higher ( $p = 0.003$ ) than that of pregnant women ( $n = 57$ ). The duration of maximum contraction in case of nulliparous women proved to be markedly longer ( $p = 0.011$ ) than during pregnancy. Regarding lifestyle factors even when BMI and constipation were involved no